DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENU
SAN JUAN, P.R. 00901-3223

HFE-35 9/3/97
638

July 17, 1997

WARNING LETTER
SJN-97-22

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jose F. Beauchamp
President & CEO
Med-Corp/Med-Care, Inc
P.O. Box 4727
San Juan, P.R. 00936

Dear Mr. Beauchamp:

During an inspection of your compressed medical gas transfilling facility, Med-Corp./Med-Care, Inc., 1378 Calaf St., Hato Rey, P.R., conducted from June 5 to June 19, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's manufacture of Oxygen, U.S.P. causing this drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to assure that drug products which do not meet established specifications are rejected in accordance with 21 CFR 211.165 (f) in that test records show that none of the lots of Oxygen U.S.P. transfilled and distributed by your firm from 2/26/97 to 6/4/97 met the minimum U.S.P. purity standard of 99.5%.

2. Failure to establish the accuracy, sensitivity and reproducibility of the test method employed for testing Oxygen, U.S.P. in accordance with 21 CFR 211.165 (e) in that the [redacted] oxygen analyzer has not been shown to be equivalent or superior to the U.S.P. procedure.

3. Failure to maintain adequate records of testing of Oxygen, U.S.P. in that:

   a) there is no documentation of the calibration of test equipment in accordance with 21 CFR 211.194 (d).

b) there was no record of purity test results for 13 cylinders of Oxygen, U.S.P.

4. Failure to establish a Quality Control unit that has the responsibility and authority to approve or reject all incoming or outgoing products and to review production and test records for completeness and accuracy in accordance with 21 CFR 211.22.

5. Failure to establish written procedures for the following:

a) receiving and transfilling of Oxygen U.S.P. in accordance with 21 CFR 211.100.

b) reconciliation of the quantities of labeling received, used and returned in accordance with 21 CFR 211.125 (c).

c) appropriate test specifications to assure that Oxygen, U.S.P. meets the required purity standards in accordance with 21 CFR 211.160 (b).

d) test equipment calibration in accordance with 21 CFR 211.160 (b)(4).

6. Failure to have a training program and to provide training on Good Manufacturing Practices to employees and supervisors in accordance with 21 CFR 211.25 (a) & (b).

7. Failure to have adequate batch production and control records for each batch of Oxygen, U.S.P. produced in accordance with 21 CFR 211.188 (b) in that:

a) records did not document each significant step of the transfilling and testing operation.

b) production records showed uninitialed cross-outs and "white-out" used to make corrections of the original.

c) there was no documentation of supervisory review of the production records.

d) the individual who performs the transfilling operation also signs as the reviewer.

We are aware that have initiated recall of all type "H" and "E" cylinders which were distributed to home care patients.

This recall is being handled by Ivonne Ayala, Recall Coordinator for this office and any information about the recall should be forwarded to her.

We are also aware that you have ceased transfilling operations until the necessary corrections can be effected. Information regarding corrective actions should be handled as indicated below.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

A copy of 21 CFR 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS is attached to this letter for your information.

Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify the San Juan District office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions without further notice. These include seizure and/or injunction.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

Samuel Jones
District Director

Enclosure
cc: Mr. Jose L. Fernandez, General Manager